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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,936	05/31/2000	Michael G. Kahn M.D. Ph.D	FAST-01000US0-WSW	5001

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EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/584,936	KAHN M.D. PH.D ET AL.	
	Examiner	Art Unit	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,31-44 and 110-139* is/are pending in the application.

4a) Of the above claim(s) *7,36,118 and 137* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-11,31-35,37-44,110-117,119-136,138 and 139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040916*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 2/22/05. Claims 1-6, 8-11, 31-35, 37-44, 110-117, 119-136, and 138-139 have been examined. Claim 139 is newly added.

Election/Restrictions

2. Applicant's election without traverse of claims 6, 34, 117, and 136 in the reply filed on 2/22/05 is acknowledged.

Claims 7, 36, 118, and 137 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/22/05.

Specification

3. The objection to the abstract is hereby withdrawn due to the amendment filed 12/22/03.

Claim Objections

4. Claims 8, 10, and 138 are objected to because of the following informalities: they depend on withdrawn claims 7 and 137. Appropriate correction is required. For purposes of applying prior art, the Examiner has considered claims 8 and 10 to be

properly dependent on claim 4 and for claim 138 to be properly dependent on claim 128.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 4-6, 10-11, 31-35, 40-44, 110-117, 119-136, and 138-139 are rejected under 35 U.S.C. 102(e) as being anticipated by Colon et al. (5,991,731).

(A) Referring to claim 1, Colon discloses at least one computer readable medium collectively carrying a machine readable database identifying (abstract of Colon):

first patient eligibility criteria for a first clinical trial protocol (col. 6, lines 39-42 of Colon); and

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow tasks (col. 6, line 39 – col. 7, line 10 of Colon).

(B) Referring to claim 2, Colon discloses wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol (col. 2, lines 5-8 of Colon).

(C) Referring to claim 4, Colon discloses wherein said first plurality of workflow tasks includes data management tasks (col. 3, lines 14-23 of Colon).

(D) Referring to claim 5, Colon discloses wherein said post-enrollment workflow tasks include post-enrollment patient management tasks (col. 6, lines 1-14 of Colon).

(E) Referring to claim 6, Colon discloses wherein said data management tasks include an instruction for a clinician to complete a specified form (col. 6, lines 55-60 of Colon).

(F) Referring to claim 10, Colon discloses wherein said data management tasks further include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(G) Referring to claim 11, Colon discloses wherein said data management tasks include an instruction to enroll a patient into a clinical trial (col. 5, lines 25-35 of Colon).

(H) Referring to claim 31, Colon discloses at least one computer readable medium collectively carrying a library identifying a plurality of machine readable protocol databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks (abstract and col. 6, line 39 – col. 7, line 10 of Colon).

(I) Referring to claim 32, Colon discloses means for providing access to individual ones of said protocol databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria (abstract of Colon).

(J) Referring to claim 33, Colon discloses wherein different ones of said protocol databases were prepared by different protocol designers (col. 1, lines 36-63 and col. 6, lines 58-66 of Colon).

(K) Referring to claim 34, Colon discloses wherein each of said protocol databases identifies (abstract of Colon):

patient eligibility criteria for the respective clinical trial protocol; and

a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks (col. 6, line 39 – col. 7, line 10 of Colon).

(L) Referring to claim 35, Colon discloses wherein each of said protocol databases further identifies preliminary patient eligibility criteria applicable to the respective clinical trial protocol (col. 2, lines 5-8 of Colon).

(M) Referring to claim 40, Colon discloses wherein different ones of said clinical trial protocols address different disease categories (col. 4, lines 49-53 and col. 6, lines 22-30 of Colon).

(N) Referring to claim 41, Colon discloses wherein each of said machine readable protocol databases includes software objects instantiated from a corresponding predefined set of object classes (Fig. 3 and col. 4, lines 3-36 of Colon).

(O) Referring to claim 42, Colon discloses wherein all of said machine readable protocol databases include software objects instantiated from a common predefined set of object classes (Fig. 3 and col. 4, lines 3-36 of Colon).

(P) Referring to claim 43, Colon discloses wherein a first one of said machine readable protocol databases includes software objects instantiated from a first predefined set of object classes, and a second one of said machine readable protocol databases includes

software objects instantiated from a second predefined set of object classes different from said first predefined set of object classes (Fig. 3 and col. 4, lines 3-36 of Colon).

(Q) Referring to claim 44, Colon discloses wherein the machine readable protocol databases are for clinical trial protocols in a plurality of disease categories, and wherein the software objects included in each given one of said machine readable protocol databases are instantiated from a set of object classes which corresponds to and is specific to the disease category of the clinical trial protocol of the given protocol database (Fig. 3, col. 4, lines 3-36, and col. 6, lines 15-30 of Colon).

(R) Referring to claim 110, Colon discloses the steps of storing in a library of clinical trial sub-protocol components, a first clinical trial sub-protocol component identifying at least one member of the group consisting of a patient eligibility criterion and a patient management protocol workflow task (abstract and col. 6, line 39 – col. 7, line 10 of Colon); and

assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library (col. 5, lines 14-25 of Colon).

(S) Referring to claim 111, Colon discloses the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks (abstract and col. 6, line 39 – col. 7, line 10 of Colon),

wherein said step of storing a plurality of databases includes said step for storing a first clinical trial sub-protocol component (col. 1, line 64 – col. 2, line 4 of Colon).

(T) Referring to claim 112, Colon discloses the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria (col. 5, lines 14-34 of Colon).

(U) Referring to claim 113, Colon discloses wherein said step of assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library comprises the steps of (col. 5, lines 14-25 of Colon):

providing read/write access to said first clinical trial sub-protocol component by a first user (col. 5, lines 25-35 and col. 6, lines 15-21 of Colon); and

providing read but not write access to said first clinical trial sub-protocol component by a second user (col. 5, lines 14-25 and col. 6, lines 34-38 of Colon).

(V) Referring to claim 114, Colon discloses wherein said first clinical trial sub-protocol component includes first and second sub-protocol sub-components (col. 6, lines 39-60 of Colon).

(W) Referring to claim 115, Colon discloses assigning a first sub-protocol sub-component level user access control to said first sub-protocol sub-component (col. 5, lines 14-25 of Colon); and

assigning a second sub-protocol sub-component level user access control to said second clinical trials sub-protocol sub-component in said library (col. 5, lines 14-25 of Colon).

(X) Referring to claim 116, Colon discloses storing in said library a second clinical trial sub-protocol component identifying at least one member of the group consisting of a

patient eligibility criterion and a protocol workflow task (col. 6, lines 39 – col. 7, line 10 of Colon); and

assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library (col. 5, lines 14-25 of Colon).

(Y) Referring to claim 117, Colon discloses wherein said first and second clinical trial sub-protocol components are both components of a common clinical trial protocol (col. 6, lines 39-60 of Colon).

(Z) Referring to claim 119, Colon discloses wherein said step of assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library comprises the step of providing read/write access to said first clinical trial sub-protocol component by a first user (col. 5, lines 14-34 and col. 6, lines 15-21 of Colon),

and wherein said step of assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library comprises the step of providing read but not write access to said second clinical trial sub-protocol component by said first user (col. 6, lines 15-16 and col. 5, lines 14-24 of Colon).

(AA) Referring to claim 120, Colon discloses a clinical trials method, comprising the steps of:

storing a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of a patient eligibility criterion and a patient

management protocol workflow task (abstract and col. 6, line 39 – col. 7, line 10 of Colon); and

providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users in accordance with predetermined sub-protocol component level access controls (col. 6, lines 15-21 of Colon).

(BB) Referring to claim 121, Colon discloses the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks (abstract and col. 6, line 39 – col. 7, line 10 of Colon), wherein said step of storing a plurality of databases includes said step of storing a plurality of clinical trial sub-protocol components (col. 1, line 64 – col. 2, line 4 of Colon).

(CC) Referring to claim 122, Colon discloses the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria (col. 5, lines 14-35 of Colon).

(DD) Referring to claim 123, Colon discloses wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users comprises the steps of (col. 5, lines 14-25 of Colon):

providing read/write access to a first one of said clinical trial sub-protocol components by a first one of said users (col. 5, lines 25-35 and col. 6, lines 15-21 of Colon);

providing read but not write access to said first clinical trial sub-protocol component by a second one of said users (col. 5, lines 14-25 and col. 6, lines 34-38 of Colon).

(EE) Referring to claim 124, Colon discloses wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users further comprises the steps of:

providing read/write access to a second one of said clinical trial sub-protocol components by said second user (col. 6, lines 15-21 of Colon).

(FF) Referring to claim 125, Colon discloses wherein a first one of said sub-protocol components includes first and second sub-protocol sub-components (col. 6, line 58 – col. 7, line 10 of Colon).

(GG) Referring to claim 126, Colon discloses the step of providing access to said clinical trials sub-protocol sub-components by each of a plurality of users in accordance with predetermined sub-protocol sub-component level access controls (col. 6, lines 15-21 of Colon).

(HH) Referring to claim 127, Colon discloses the step of receiving said sub-protocol components from a plurality of different protocol designers (col. 6, lines 15-21 and col. 1, lines 36-47 of Colon).

(II) Referring to claim 128, Colon discloses at least one computer readable medium collectively carrying a library identifying a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks, said library further identifying sub-protocol component level user access controls for at least a subset of said sub-protocol components (abstract, col. 6, line 39 – col. 7, line 10, and col. 6, lines 15-21 of Colon).

(JJ) Referring to claim 129, Colon discloses wherein said library further identifies a plurality of protocol databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and patient management protocol workflow tasks, wherein one of said clinical trial sub-protocol components is a component of one of said clinical trial protocols (abstract, col. 6, line 39 – col. 7, line 10, and col. 5, lines 14-24 of Colon).

(KK) Referring to claim 130, Colon discloses wherein said library further identifies protocol-level access controls which control access to individual ones of said databases by each of a plurality of clinical sites (col. 5, lines 14-34 of Colon).

(LL) Referring to claim 131, Colon discloses wherein said sub-protocol component level user access controls include a first control which provides read/write access to a first one of said clinical trial sub-protocol components by a first user and which further provides read but not write access to said first clinical trial sub-protocol component by a second user (col. 5, lines 14-25 and col. 6, lines 15-38 of Colon).

(MM) Referring to claim 132, Colon discloses wherein said sub-protocol component level user access controls further include a third control which provides read/write access to a second one of said clinical trial sub-protocol components by said second user (col. 5, lines 26-35 of Colon).

(NN) Referring to claim 133, Colon discloses wherein a first one of said sub-protocol components includes first and second sub-protocol sub-components (col. 6, line 58 – col. 7, line 10 of Colon).

(OO) Referring to claim 134, Colon discloses wherein said sub-protocol component level user access controls further include sub-protocol sub-component level user access controls (col. 6, lines 15-21 of Colon).

(PP) Referring to claim 135, Colon discloses wherein first and second ones of said sub-protocol components were prepared by different protocol designers (col. 6, lines 15-21 and col. 1, lines 36-47 of Colon).

(QQ) Referring to claim 136, Colon discloses wherein first and second ones of said sub-protocol components are both components of a common clinical trial protocol (col. 6, lines 39-60 of Colon).

(RR) Referring to claim 138, Colon discloses wherein said first and second clinical trial protocols address different disease categories (col. 4, lines 49-53 and col. 6, lines 22-30 of Colon).

(SS) Referring to claim 139, Colon discloses wherein said post-enrollment workflow tasks include patient management tasks (col. 6, lines 1-14 of Colon).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Cimino ("Distributed cognition and knowledge-based controlled medical terminologies").

(A) Referring to claims 3, 37, 38, and 39, Colon does not disclose wherein said database identifies a term by reference to a controlled medical terminology database, wherein at least one of said protocol databases identifies a term by reference to a controlled medical terminology database, wherein each of said protocol databases identifies a term by reference to a controlled medical terminology database, and wherein each of a plurality of said protocol databases identifies a term by reference to a common controlled medical terminology database.

Cimino teaches that controlled medical terminologies (CMTs) are at the heart of most medical systems (pages 154 & 162 of Cimino).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cimino within Colon. The motivation for doing so would have been to enable data sharing and coordination of multiple applications (page 161 of Cimino).

9. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al. (5,991,731) in view of Breitfeld et al. ("Pilot Study of a Point-of-use Decision Support Tool for Cancer Clinical Trials Eligibility").

(A) Referring to claims 8 and 9, Colon does not disclose wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before said instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

Breitfeld discloses wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before said instruction to obtain informed consent and wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent (page 468 of Breitfeld).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Breitfeld within Colon. The motivation for doing so would have been so that eligible patients are informed of what will happen during the study (page 472 of Breitfeld).

Response to Arguments

10. Applicant's arguments (filed 12/22/03) with respect to claims 1-11, 31-44, 110-138 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches research data collection and analysis (US 6,196,970 B1); a computerized system for conducting medical studies (US 6,839,678 B1); a computer network system and method for managing documents (5,666,490); and an integrated care management system (US 2001/0051882 A1).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

In
5-26-06

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER